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| APPLICATION NO. | FIL | ING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|------------|------------|----------------------|--------------------------|------------------|
| 10/603,429 | 06/24/2003 | | Zifei Wang | A03P1031 | 4308 |
| 36802 | 7590 | 01/04/2006 | | EXAMINER | |
| PACESET | • | | KAHELIN, MICH | KAHELIN, MICHAEL WILLIAM | |
| 15900 VALLEY VIEW COURT SYLMAR, CA 91392-9221 | | | | ART UNIT PAPE | |
| | | | | 3762 | |

DATE MAILED: 01/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | | |
|---|---|---------------------|--------|--|--|--|--|
| Office Action Commons | 10/603,429 | WANG ET AL. | | | | | |
| Office Action Summary | Examiner | Art Unit | | | | | |
| | Michael Kahelin | 3762 | | | | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the c | orrespondence ad | Idress | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | | |
| Status | | | | | | | |
| 1) Responsive to communication(s) filed on 13 De | ecember 2005. | | | | | | |
| · — | action is non-final. | | | | | | |
| 3) Since this application is in condition for allowar | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | | |
| closed in accordance with the practice under E | | | | | | | |
| Disposition of Claims | | | | | | | |
| · | | | | | | | |
| , | 4) ☐ Claim(s) 1-20 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5)⊠ Claim(s) <u>16,19 and 20</u> is/are allowed. | | | | | | | |
| 6) Claim(s) 1,2,13-15,17 and 18 is/are rejected. | | | | | | | |
| 7)⊠ Claim(s) <u>3-12</u> is/are objected to. | | | | | | | |
| 8) Claim(s) are subject to restriction and/o | r election requirement | | | | | | |
| | olocion roquiromoni. | | | | | | |
| Application Papers | | | | | | | |
| 9) The specification is objected to by the Examine | | | | | | | |
| 10) The drawing(s) filed on is/are: a) acce | | | | | | | |
| Applicant may not request that any objection to the | | | | | | | |
| Replacement drawing sheet(s) including the correct | | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | | |
| 12) ☐ Acknowledgment is made of a claim for foreign a) ☐ All b) ☐ Some * c) ☐ None of: | priority under 35 U.S.C. § 119(a) | -(d) or (f). | | | | | |
| 1. Certified copies of the priority document | s have been received. | | | | | | |
| 2. Certified copies of the priority document | s have been received in Applicati | on No | | | | | |
| 3. Copies of the certified copies of the prior | rity documents have been receive | ed in this National | Stage | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
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| | | | | | | | |
| Attachment(s) | | | | | | | |
| 1) Notice of References Cited (PTO-892) | 4) Interview Summary | (PTO-413) | | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date. | | | | | | | |
| 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 11212005. 5) Notice of Informal Patent Application (PTO-152) 6) Other: | | | | | | | |
| S Patent and Trademark Office | | | | | | | |

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REQUEST FOR INFORMATION

1. Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application. Please provide Applicant's definition of T-wave, specifically when the T-wave ends (where the ventricular repolarization end as it relates to the claimed limitation of "subsequent to ventricular repolarization"). Examiner has interpreted the end of a T-wave (repolarization) to be the point where the wave returns to baseline (see US 6,625,490, McClure et al., Fig. 8B, "Tend" and US 6,370,423, Guerrero et al., col. 7, line 17). Please note that this Office Action is based on this interpretation, and a definition contrary to this interpretation will warrant a new consideration of the application and prior art. After reviewing the specification, the disclosure seems to indicate that some energy of the T-wave is used to determine ischemia and, therefore, detection of ischemia would also require some T-wave detection to be necessary. Is this correct?

- 2. In responding to those requirements that require copies of documents, where the document is a bound text or a single article over 50 pages, the requirement may be met by providing copies of those pages that provide the particular subject matter indicated in the requirement, or where such subject matter is not indicated, the subject matter found in applicant's disclosure.
- 3. The fee and certification requirements of 37 CFR 1.97 are waived for those documents submitted in reply to this requirement. This waiver extends only to those

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documents within the scope of this requirement under 37 CFR 1.105 that are included in the applicant's first complete communication responding to this requirement. Any supplemental replies subsequent to the first communication responding to this requirement and any information disclosures beyond the scope of this requirement under 37 CFR 1.105 are subject to the fee and certification requirements of 37 CFR 1.97.

- 4. The applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained may be accepted as a complete reply to the requirement for that item.
- 5. This requirement is an attachment of the enclosed Office action. A complete reply to the enclosed Office action must include a complete reply to this requirement.

 The time period for reply to this requirement coincides with the time period for reply to the enclosed Office action.

DETAILED ACTION

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- 7. Claims 1, 2, 13, 17, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Guerrero et al. (US 6,370,423 hereinafter "Guerrero").
- 8. In regards to claims 1 and 18, Guerrero discloses a method comprising receiving electrical signals, identifying segments of the signals after repolarization and before depolarization (col. 8, line 8-25) and detecting ischemia based on the identified segments (col. 8, line 58). Examiner is interpreting detection "based" on the segments because the segments are used for detection. It is noted that the segments can be used anywhere in the detecting process and will meet the claim limitation of detecting cardiac ischemia "based" on the segments.
- 9. In regards to claim 2, ischemia is detected to predict subsequent acute myocardial infarction (col. 14, line 31).
- 10. In regards to claims 13 and 17, the invention generates an alarm (col. 17, line 28).

Claim Rejections - 35 USC § 103

- 11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guerrero in view of Fischell (US 4,295,474 hereinafter "Fischell"). Guerrero discloses the essential features of the claimed invention except for a "tickle" alarm and an external alarm. Fischell teaches of providing an implantable device with external and tickle alarms (col. 4, line 47) to provide an indication to the patient or a second party. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Fischell's invention with a "tickle" and external alarm to provide an indication to the patient or a second party.

Allowable Subject Matter

- 14. Claims 16, 19, and 20 are allowed.
- 15. Claims 3-12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MWK

GEORGE R. EVANISKO PRIMARY EXAMINER

FRÉDERICK R. SCHMIDT DIRECTOR

TECHNOLOGY CENTER 3780